

510(k) SUMMARY

K961425

**1. APPLICANT**

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**2. DEVICE NAME**

PROPRIETARY/TRADE NAME: Bio Compression Cold Flo®

COMMON/USUAL NAME: Cold Therapy Massager, Single Chamber  
Intermittent and Multi-Chamber Sequential Models

CLASSIFICATION NAME: Cold Water Circulating Pack/Powered Inflatable  
Tube Massager

**3. PREDICATE DEVICE**

The Bio Compression Cold Flo® is substantially equivalent in design, materials and use to the Jobst Cryo/Temp™. According to Jobst, the Cryo/Temp™ device was legally marketed by that company prior to May 28, 1976. Like the Bio Compression Cold Flo®, the Jobst Cryo/Temp™ provides a simultaneous application of cold therapy along with controlled pressure.

Two other devices also serve as predicates for the Cold Flo®. The Cold Flo® is substantially equivalent to the Tempacure, which provides cold or hot therapy, (510(k) number K921540), and the Sequential Circulator, which provides

sequential compression therapy (sold by Bio Compression prior to May 28, 1976). The Cold Flo® combines the functions of each of these predicate devices, and it is substantially equivalent in design, materials and use to them.

#### **4. DESCRIPTION OF THE COLD FLO®**

The Cold Flo® is a device that combines the function of two devices traditionally used for providing cold therapy and massage therapy. Like a Powered Inflatable Tube Massager, the Cold Flo® provides massage therapy through a pump providing compression to the affected limb. This pressure, depending on the Cold Flo® model, is either sequential or intermittent. At the same time, the Cold Flo® delivers cold therapy by circulating cold water through the limb sleeve, like a Cold Water Circulating Pack. The single version contains one chamber that inflates or deflates to provide intermittent pressure. The sequential version contains 3 chambers that inflate and deflate sequentially (from distal to proximal), and an inner sleeve through which the cold water flows. The Cold Flo® sleeve is made of nylon and poly-ether-urethane.

#### **4. INTENDED USE**

The COLDFLO™ models combine cold and compression therapies. This combination is intended to provide a temporary increase in the circulation of fluids from the treated limb, reducing minor pain and swelling. The device may also enhance healing secondary to the reduction of swelling in the limb.

#### **5. TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE**

The Cold Flo® is substantially equivalent in design, materials and use to the Jobst Cryo/Temp™ as well as to the Tempacure and the Sequential Circulator Model 2000. A table comparing the design, material, physical characteristics, and intended uses of the devices is attached as Exhibit A.

**COLD FLO® COMPARISON:  
COLD CIRCULATING DEVICES AND POWERED INFLATABLE TUBE MASSAGERS**

<b>PARAMETER</b>	<b>BIO COMPRESSION COLD FLO®</b>	<b>JOBST CRYO/TEMP</b>	<b>BIOCOMPRESSION SEQUENTIAL CIRCULATOR</b>	<b>TEMPACURE COOLING/HEATING THERAPY DEVICE (K921540)</b>
Intended Use	Cold and compression therapy to temporarily increase circulation, reduce edema, and alleviate pain in the treated limb. May enhance healing secondary to reduction of edema.	Cold and pressure therapy for fracture, contusions, sprains, muscle spasms and edema	Pressure therapy for primary and secondary lymphedema, venous and lymphatic insufficiency, and post-traumatic edema	To provide hot and cold therapy
Energy Source	120V 60Hz		Starting Amps: 110 V, 1.42 Amps, 156.20 Watts Maximum Running Amps: 110V, 0.78 Amps, 85.80 Watts	90-270V 40-60Hz
Materials	Nylon and poly-ether-urethane (sleeve)		Nylon reinforced polyurethane.	Polyvinylchloride (sleeve)
Anatomical Sites	Arms and legs	Arms and legs	Arms and legs	Arms, legs, or other discrete body locations
Water Capacity/Flow Rate	1250 ml fluid capacity; flow rate of 16-20 oz. per minute	Flow rate of 16 oz. per minute	N/A	6 oz. reservoir capacity; flow rate of 10-15 gallons per hour
High/low Temperature	Room temperature to 40°	70° F to 40° F	N/A	107°F to 34°F
High/Low Pressures	30-125 mm/Hg	10-120 mm/Hg	30-180 mm Hg	N/A
Filling/Deflation Times	Inflation time: 60 seconds. Deflation time: 12-15 seconds.	Inflation time: 90 seconds. Deflation time: 30 seconds.	Inflation time: 24-60 seconds Deflation time: 6-72 seconds	N/A